PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Form PCT/IPEA/416	
PU02103-PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE2003/001434	12.09.2003	31.10.2002
International Patent Classification (IPC) or national classification and IPC		
C07C 275/00, C07D 213/81, A61P 37/00, C07D 233/34, A61K 31/17, C12Q 1/58, G01N 33/62 // C08G 71/02, A01N 47/28, C07K 16/00		
Applicant		
Amersham Biosciences AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17.05.2004	14.02.2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Fernando Farieta/EÖ Telephone No. +46 8 782 25 00

INTERNATIONAL PRE[redacted]NARY REPORT ON PATENTABILITY

Int[redacted]onal application No.
PCT/SE2003/001434

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2003/001434

Box No. II Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

   ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

The priority is considered to be valid.

INTERNATIONAL PRE[redacted]NARY REPORT ON PATENTABILITY

International application No.
PCT/SE2003/001434

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 20

because:

☒ the said international application, or the said claims Nos. 20
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 13-14
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 13-14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2003/001434

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-12, 15-19 and 21 (Y)	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12, 15-19 and 21 (N)	NO
Industrial applicability (IA)	Claims	1-12, 15-19 and 21 (Y)	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents have been found to be relevant:

D1: EP 0 743 067 A2
"Use of urea and thiourea compounds for elimination or detoxification of superantigens from body fluids"

D2: WO 02/076930 A2
"Substituted diarylureas as stimulators for FAS-mediated apoptosis".

D3: "A highly sensitive and rapid ELISA for the arylurea herbicides diuron, monuron and linuron". Schneider et al J. Agric. Food. Chem. Vol 42(1994)p413-422.

Novelty (N)

The claimed invention relates to arylurea compounds and separation matrix for affinity chromatography thereof.

The problem to be solved is to develop alternative IgG-binding ligands in order to avoid the disadvantages of known IgG-binding ligands (pages 5-7 description).
The applicant has identified a binding site that exhibits the spatial conformation specific for human kappa IgGs of all subtypes (page 5, last paragraph). The claimed invention provides ligands to the identified binding site (Arylureas on Figure 3).

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

Document D1 discloses material which has a highly selective absorption of super antigens containing urea bonds or thiourea bonds. Figure 1 in document D1 shows the advantages of using urea-bonds compared to benzene-rings in separation matrixes. The formulas I-III show alternative urea compounds according to claims 4, 13, 24 and 32.

Document D2 comprises urea compounds (formula I) for bioassays (claim 20) and for the treatment of autoimmune diseases.

Document D3 disclose diuron, monuron and linuron compounds (figure 1 compounds 6-10), arylurea compounds useful as enzyme tracers or coating antigens (page 414, first column).

The claimed arylurea compounds and separation matrix for affinity chromatography are not considered to be within the scope of documents D1-D3, therefore claims 2-12, 15-19 and 20 are considered to be novel.

The feature arylurea is merely one of several straightforward possibilities from the similar structures presented in documents D1-D3, which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

The invention according to claims 2-12, 15-19 and 21 is not considered to involve an inventive step.

INTERNATIONAL PRE[redacted]NARY REPORT ON PATENTABILITY

Int[redacted]tional application No.
PCT/SE2003/001434

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

(P,X) "QSAR and classification of murine and human soluble epoxide hydrolase inhibition by urea-like compounds" J Med Chem Vol 46 (2003) p1066-1080 tables I-II

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Present claim 1 relates to urea compounds defined by reference to a desirable characteristic or property, namely "compound having affinity for human IgG of k-type".
The claim cover all urea compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and / or disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful examination over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lacks clarity (Article 6 PCT).

Consequently, the examination has been carried out for those parts of the claim which appear to be clear, supported and disclosed, namely those parts relating to the urea compounds in figure 3.